



Karl Storz Imaging, Inc. 175 Cremona Drive, Goleta, CA 93117

510(k) SUMMARY

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**Submitted By:
(Contact person)**

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175 Cremona Drive
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Summary Date:

August 14, 1996

Trade Name:

Optronics EPIC Color Television Camera System, Model
S97340

Device Name:

Video camera accessory for AC-powered Slit Lamp
Biomicroscope

Classification Name:

Ophthalmic camera/21 CFR 886.1120
AC-powered slitlamp biomicroscope/21 CFR 886.1850

Predicate Devices:

Haag-Streit Model BQ Slit Lamp w/accessories
Haag-Streit Model BM Slit Lamp w/accessories

Device Description:

The Optronics EPIC System consists of a camera and a video processor. The camera consists of a camera head with eyepiece and beamsplitter and an integral cable for electronic transmission of signals and power. The camera head consists of an outer aluminum shell housing the video sensor and optical elements. The cable is permanently attached to the camera head and connects to the processor. The processor consists of a finished aluminum housing containing the power supply, circuit boards, and interconnections necessary to process the video image.

Intended Use:

The Optronics EPIC System is intended for use as an accessory to a slit lamp biomicroscope, providing enhanced imaging of the eye for ophthalmic examination, diagnosis, treatment definition and clarification, and patient education/proof of treatment need.



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**Comparison to
Predicate Devices:**

The Optronics EPIC is equivalent to the Haag-Streit 900 BQ and 900 BM with respect to their intended uses. We believe, however, that the EPIC provides the practitioner with greater flexibility and ease of use by combining the biomicroscope interface and camera into a 10X eyepiece which utilizes a 50/50 beam splitter to allow simultaneous viewing both on the video monitor and through the eyepiece. For a comparison of video system performance, please refer to the following table.

<u>Characteristic</u>	<u>EPIC</u>	<u>Haag-Streit 900 BQ</u>	<u>Haag-Streit 900 BM</u>
CCD Type	1/4 inch	1/2 inch	1/2 inch
Resolution	470 TV lines	450 TV lines	450 TV lines
Sensitivity	2 lux	10 lux	10 lux
Beam splitter	50/50	50/50 or 70/30 (selectable)	Video adaptor is a separate microscope
Eyepiece magnification	10X	6.3, 10, 16, 25, 40X	6.3, 10, 16, 25, 40X